PATENT COOPERATION TREATY

| | _ | | | |
|-------|---|---|-----|------|
| REC'D | 1 | 0 | MAR | 2005 |
| WIPO | _ | | | PCT |

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/ | | | | |
|--|-------------------------------|--|--|--|
| | 416) | | | |
| 19487/01111 International application No. International filing date (day/month/year) Priority date (day/month/year) | | | | |
| 17 Type 2002 (17 06 2002) | | | | |
| PCT/US03/19029 17 June 2003 (17.06.2003) 17 June 2002 (17.06.2002) International Patent Classification (IPC) or national classification and IPC | | | | |
| | | | | |
| IPC(7): C01B 11/00; C12N 9/00; B29D 22/00 and US Cl.: 252/186.1,186.2,186.25; 435/183,187,188,189,190,191,192; 428/34.1,34.8,35.2,35.4,35.5,35.7,36.1,36.6 | | | | |
| Applicant | | | | |
| NUTRICEPTS, INC. | | | | |
| This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. | | | | |
| 2. This REPORT consists of a total of 5 sheets, including this cover sheet. | | | | |
| This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheets. | | | | |
| 3. This report contains indications relating to the following items: | | | | |
| | | | | |
| I Basis of the report | | | | |
| II Priority | | | | |
| III Non-establishment of report with regard to novelty, inventive step and industrial applicability | | | | |
| IV Lack of unity of invention | | | | |
| V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | |
| VI Certain documents cited | | | | |
| VII Certain defects in the international application | | | | |
| VIII Certain observations on the international application | | | | |
| | | | | |
| Date of submission of the demand Date of completion of this report | | | | |
| 28 October 2003 (28.10.2003) 23 February 2005 (23.02.2005) | 23 February 2005 (23.02.2005) | | | |
| Name and mailing address of the IPEA/US Authorized officer / / / / / / / / / / / / / / / / / / / | | | | |
| Mail Stop PCT, Attn: IPEA/US | | | | |
| Commissioner for Patents P.O. Box 1450 Harold Pyon Harold Pyon Oct. 1450 | | | | |
| Alexandria, Virginia 22313-1450 Telephone No. 703-368-0661 Facsimile No. (703)305-3230 | | | | |

Form PCT/IPEA/409 (cover sheet)(July 1998)

| International application No. | |
|-------------------------------|--|
| PCT/US03/19029 | |

| T | Rocie | s of the report | | | |
|----|-----------|--|--|--|--|
| | | regard to the elements of the international application:* | | | |
| 1. | With | the international application as originally filed. | | | |
| | \bowtie | | | | |
| | | the description: pages 1-17 as originally filed | | | |
| | | pages NONE, filed with the demand | | | |
| | | pages NONE , filed with the letter of | | | |
| | \square | the claims: | | | |
| | | | | | |
| | | pages NONE, as originally filed pages NONE, as amended (together with any statement) under Article 19 | | | |
| | | pages NONE , filed with the demand | | | |
| | | pages 18-21, filed with the letter of 05 April 2004 (05.04.2004) | | | |
| | | the drawings: | | | |
| | ш | pages NONE, as originally filed | | | |
| | | pages NONE, filed with the demand | | | |
| | | pages NONE, filed with the letter of | | | |
| | | the sequence listing part of the description: | | | |
| | ш | pages NONE, as originally filed | | | |
| | | pages NONE , filed with the demand | | | |
| | | pages NONE , filed with the letter of | | | |
| 2 | lang | th regard to the language, all the elements marked above were available or furnished to this Authority in the guage in which the international application was filed, unless otherwise indicated under this item. se elements were available or furnished to this Authority in the following language which is: the language of a translation furnished for the purposes of international search (under Rule23.1(b)). | | | |
| | <u> </u> | | | | |
| | <u></u> | the language of publication of the international application (under Rule 48.3(b)). | | | |
| | L | the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3). | | | |
| 3 | . Wi | th regard to any nucleotide and/or amino acid sequence disclosed in the international application, the remains a remains and the remains are remained out on the basis of the sequence listing: | | | |
| | | contained in the international application in printed form. | | | |
| | | filed together with the international application in computer readable form. | | | |
| | | furnished subsequently to this Authority in written form. | | | |
| | | furnished subsequently to this Authority in computer readable form. | | | |
| | | The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. | | | |
| | | The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished. | | | |
| ۱, | f. [| The amendments have resulted in the cancellation of: | | | |
| | | the description, pages NONE | | | |
| | | the claims, Nos. NONE | | | |
| | | the drawings, sheets/fig NONE | | | |
| | 5. [| This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).** | | | |
| 1 | this re | lacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to it port as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17). The replacement sheet containing such amendments must be referred to under item 1 and annexed to this report. | | | |

Form PCT/IPEA/409 (Box V) (July 1998)

International application No. PCT/US03/19029

| V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | |
|---|------------------|--------------------------|--------|--|
| 1. STATEMENT | | |] | |
| Novelty (N) | Claims | 5, 11-19, 24 | YES | |
| 2.0.0000 | | 1-4, 6-10, 20-23, 25, 26 | NO | |
| | | | VEC | |
| Inventive Step (IS) | Claims Claims | NONE | YES NO | |
| | Clanis | 1-20 | | |
| Industrial Applicability (IA) | Claims | 1-26 | YES | |
| | Claims | NONE | NO | |
| 2. CITATIONS AND EXPLANATIONS Please See Continuation Sheet | | | | |
| | | | | |
| | | | • | |
| | | | | |
| | | | | |

International application No. PCT/US03/19029

| | <u> </u> | |
|--|------------------------------------|--|
| Supplemental Box (To be used when the space in any of the preceding boxes is not sufficient) | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| V. 2. Citations and Explanations: | | |
| US 5,278,044 (SAN GEORGE et al) 11 January 1994, see column 2, line 58-0 | column 3, line 10 | |
| Claims 1 4 6 10 20 23 25 and 26 lack novelty under PCT Article 33(2) as h | eing anticipated by Strobel et al. | |

Claims 1-4, 6-10, 20-23, 25 and 26 lack novelty under PCT Article 33(2) as being anticipated by Strobel et al.

Strobel et al teach an oxygen scavenging composition comprising an enzyme system, an energy source for the enzyme system (e.g. glucose) and a buffering agent (col. 16, lines 10-51). In regard to claims 2-4, Strobel et al teach that the enzyme system comprises glucose oxidase (col. 16, lines 33-44). In regard to claims 6 and 7, Strobel et al teach that the energy source comprises glucose, fructose, lactose or maltose (col. 16, lines 33-42). In regard to claims 8 and 9, Strobel et al teach that the energy source comprises dextrose (col. 33, lines 2-3). In regard to claim 10, Strobel et al teach that the enzyme system comprises glucose oxidase (col. 16, lines 33-44). In regard to claim 20, Strobel et al teach that the composition is contained in a nonwoven web to form an absorbent pad (col. 33, 46-48 and 57-59); therefore, the nonwoven web enclosure is necessarily water permeable since the pad formed in part by the web is absorbent. In regard to claims 21-23, the nonwoven web enclosing the composition is considered to be a bag or sachet. In regard to claim 25, the composition is necessarily in a three dimensional form. In regard to claim 26, Strobel et al teach an enzymatic oxygen scavenging system comprising an oxidoreductase enzyme (glucose oxidase, col. 16, lines 33-44) and an effective amount of a buffering agent for buffering the enzymatic oxygen scavenging system (col. 16, lines 10-51).

Claims 5 and 11 lack an inventive step under PCT Article 33(3) as being obvious over Strobel et al in view of Stougaard et al.

Strobel et al teach the oxygen scavenging composition as discussed above. Strobel et al fail to teach that the composition comprises hexose oxidase. Stougaard et al, however, disclose that hexose oxidase can convert a broader range of sugar substrates than glucose oxidase (col. 1, lines 19-28). Therefore, one of ordinary skill in the art would have recognized to have replaced the glucose oxidase of Strobel et al with the hexose oxidase of Stougaard et al in order to enable the composition of Strobel et al to convert a broader range of sugar substrates than it is capable of with glucose oxidase as taught by Stougaard et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the glucose oxidase of Strobel et al with the hexose oxidase of Stougaard et al in order to enable the composition of Strobel et al to convert a broader range of sugar substrates than it is capable of with glucose oxidase as taught by Stougaard et al.

Claims 12-15 and 17-19 lack an inventive step under PCT Article 33(3) as being obvious over Strobel et al.

Strobel et al teach the oxygen scavenging composition as discussed above.

Strobel et al fail to teach that the glucose oxidase, catalase, glucose source and buffer are present in the claimed amount ranges, and that the glucose and buffer are present in the claimed molar ratios, but it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined the optimal amount of glucose oxidase, catalase, glucose source and buffer, and the optimal glucose to buffer molar ratio, required to achieve the desired oxygen scavenging capability of the composition depending on the desired end result.

International application No. PCT/US03/19029

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Claim 16 lacks an inventive step under PCT Article 33(3) as being obvious over Strobel et al in view of San George et al.

Strobel et al teach the oxygen scavenging composition as discussed above. Strobel et al fail to teach that the buffer comprises sodium bicarbonate. San George et al, however, establish that sodium bicarbonate is a well known component of a buffer system (col. 2, line 58- col. 3, line 10). Therefore, one of ordinary skill in the art would have recognized to have used sodium bicarbonate as a component of the buffer system of Strobel et al since sodium bicarbonate is a well known component of a buffer system as taught by San George et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have to have used sodium bicarbonate as a component of the buffer system of Strobel et al since sodium bicarbonate is a well known component of a buffer system as taught by San George et al.

Claim 24 lacks an inventive step under PCT Article 33(3) as being obvious over Strobel et al in view of Akao et al.

Strobel et al teach the oxygen scavenging composition as discussed above. Strobel et al fail to teach that the composition is contained in laminate product receiving structure. Akao et al., however, disclose a packaging enclosure (Fig. 7 and 8) formed of laminate sheeting (Fig. 1-6). One of ordinary skill in the art would have recognized to have contained the composition in a laminate product receiving structure since is it is more than notoriously well known to use laminate sheeting as the stock material from which packaging enclosures are formed as taught by Akao et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have contained the composition in a laminate product receiving structure since is it is more than notoriously well known to use laminate sheeting as the stock material from which packaging enclosures are formed as taught by Akao et al.

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by Akao et al.

Akao et al teach an oxygen scavenging composition comprising an enzyme system, an energy source for the enzyme system (e.g. glucose) and a buffering agent (sodium bicarbonate, which is characterized as a buffer in Applicant's claim 16) (col. 30, line 62-col. 31, line 22, note col. 31, lines 7-8). In regard to claim, Akao et al teach that the enzyme system comprises glucose oxidase (col. 31, line 2), a oxidoreductase enzyme.

Claims 1-3 lack novelty under PCT Article 33(2) as being anticipated by Hitzman.

Hitzman teach an oxygen scavenging composition comprising an enzyme system (an oxidoreductase enzyme, col. 5, line 66), an energy source for the enzyme system (col. 6, lines 43-47) and a buffering agent (col. 8, line 49). Hitzman teach that the composition comprises catalase (col. 6, lines 16-18).

RESPONSE TO APPLICANT'S ARGUMENTS

Applicant's arguments presented on pages 7-11 of the Amendment filed April 5, 2004 have been fully considered but are not persuasive. The recitation added in claim 1 in the Amendment filed April 5, 2004 is an intended use phrase which has not been given patentable weight since a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. The distinction between use of the buffer of Strobel et al during processing and the buffer of the instant application during oxygen scavenging is a matter of intended use and is not germane to the patentability of the claimed composition. The water-miscible solvent system of Strobel et al reads on the composition claimed in the instant application. Applicant argues that the water-miscible solvent of Strobel et al is not part of the porous structure of Strobel et al, but the porous structure of Strobel et al does not correspond to the claimed composition, the water-miscible solvent system of Strobel et al corresponds to the claimed composition.

Applicant argues that the composition of Hitzman does not include a buffering agent, but instead includes an aqueous buffer; Examiner affords no distinction between the terms "buffering agent" and "buffer", and Applicant apparently neither does since the two terms are used interchangeably in Applicant's claims (compare, e.g., claim 1 with claims 15 and 16)

Applicant argues that Akao et al does not anticipate the claims since Akao et al does not teach a mixture comprising both sodium bicarbonate and enzymes, but because Akao et al uses the phrase "mixture compositions of iron and at least one material selected from..." (col. 31, lines 12-13), a mixture of iron, sodium bicarbonate and enzymes falls within the scope of the teaching of Akao et al at col. 31, lines 7-22. The use of "at least one" at col. 31, line 13 does not limit the teaching of Akao et al to solely one listed component as Applicant alleges.

2017

11/16/04 TUE 12:22 FAX 612 331 2239

character.

1. (Currently Amended) An oxygen scavenging composition for enhancing shelf-life of a packaged product, said composition comprising an enzyme system, a suitable energy source for said enzyme system, and a buffering agent for neutralizing acid produced during enzymatic consumption of said energy source and maintaining a stable pH during said enzymatic consumption, said composition being suitable for direct application to the product of the packaged product with no consumer detectable change in product

NRS

- 2. (Original) The oxygen scavenging composition of claim 1 wherein said enzyme system comprises an oxidoreductase enzyme.
- 3. (Original) The oxygen scavenging composition of claim 2 wherein said enzyme system further comprises catalase.
- 4. (Original) The oxygen scavenging composition of claim 3 wherein said oxidoreductase enzyme comprises glucose oxidase.
- 5. (Original) The oxygen scavenging composition of claim 3 wherein said oxidoreductase enzyme comprises hexose oxidase.
- 6. (Original) The oxygen scavenging composition of claim 3 wherein said suitable energy source comprises a reducing sugar.

-14-

I۶

21018

11/16/04 TUE 12:22 FAX 612 331 2239

7. (Original) The oxygen scavenging composition of claim 6 wherein said reducing sugar is selected from the group consisting of glucose, galactose, fructose, xylose, arabinose, mannose, rhamnose, maltose, isomaltose, lactose, and cellobiose.

NRS

- 8. (Original) The oxygen scavenging composition of claim 7 wherein said suitable energy source comprises a glucose source.
- 9. (Original) The oxygen scavenging composition of claim 8 wherein said glucose source comprises dextrose.
- 10. (Original) The oxygen scavenging composition of claim 9 wherein said oxidoreductase enzyme comprises glucose oxidase.
- 11. (Original) The oxygen scavenging composition of claim 9 wherein said oxidoreductase enzyme comprises hexose oxidase.
- 12. (Original) The oxygen scavenging composition of claim 10 wherein said glucose oxidase is present in an amount of about 1 and 100 activity units (U) per gram.
- 13. (Currently Amended) The oxygen scavenging composition of claim 8 wherein said catalase is present in an amount of about 1 and 300 activity units (U) per gram.

-15-

19

@019

11/16/04 TUE 12:22 FAX 612 331 2239

NRS

- 14. (Original) The oxygen scavenging composition of claim 13 wherein said glucose source is present in an amount of about 20 to 99 weight percent.
- 15. (Original) The oxygen scavenging composition of claim 14 wherein said buffer is present in an amount of about 1 to 80 weight percent of said composition.
- 16. (Original) The oxygen scavenging composition of claim 15 wherein said buffer comprises sodium bicarbonate.
- 17. (Original) The oxygen scavenging composition of claim 14 wherein a molar ratio of glucose to buffering agent is in the range of about 0.5 to 1.
- 18. (Original) The oxygen scavenging composition of claim 14 wherein a molar ratio of glucose to buffering agent is in the range of about 10 to 1.
- 19. (Original) The oxygen scavenging composition of claim 18 wherein said molar ratio of glucose to buffering agent is in the range of about 2 to 1.
- 20. (Original) The oxygen scavenging composition of claim 6 wherein

-16-

Zo

@020

11/16/04 TUE 12:22 FAX 612 331 2239

NRS

said composition is contained in a water permeable enclosure.

- 21. (Original) The oxygen scavenging composition of claim 20 wherein said enclosure is a bag.
- 22. (Original) The oxygen scavenging composition of claim 20 wherein said enclosure is a resealable bag.
- 23. (Original) The oxygen scavenging composition of claim 20 wherein said enclosure is a sachet.
- 24. (Original) The oxygen scavenging composition of claim 6 wherein said composition is contained in laminate product receiving structure.
- 25. (Original) The oxygen scavenging composition of claim 6 wherein said composition is embodied in a three dimensional form.
- 26. (New) An enzymatic oxygen scavenging system comprising an oxidoreductase enzyme and an effective amount of a buffering agent for buffering said system during enzymatic activity in furtherance of oxygen scavenging.

-17-

21